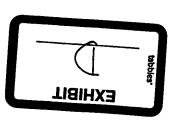
THE OFFICE OFFICE OF THE OFFIC

Examination Issues: Immunology

Yvonne (Bonnie) Eyler Quality Assurance Specialist Technology Center 1600 USPTO (571) 272-0871 Yvonne.Eyler@uspto.gov



Written Description

Antibodies





Written Description

35 U.S.C. § 112, first paragraph, requires a "written description of the as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" requirement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant invention" which is separate and distinct from the enablement must also convey with reasonable clarity to those skilled in the art that, inquiry, whatever is now claimed.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 ((Fed. Cir. 1991) (emphasis in original).



Claim Set (Noelle)

- fragment thereof which specifically binds "Claim 51. A monoclonal antibody or CD40CR."
- CD40CR is expressed by activated human T "Claim 52. The monoclonal antibody or fragment of Claim 51, wherein said cells."
- Noelle v. Lederman, 355 F.3d 1343, 1346 (Fed. Cir. 2004).



The Specification (Noelle)

- Disclosed isolated mouse CD40CR.
- Disclosed a monoclonal antibody raised to the mouse CD40CR.
- CD40CR antigen or the antibody thereto No structural elements of the human were disclosed.



because there may be unpredictability in the "A patentee of a biotechnological invention cannot necessarily claim a genus after only those specifically enumerated. See Enzo Biochem II, 323 F.3d at 965; Regents, 119 F.3d at 1568." Noelle, 355 F.3d at results obtained from species other than describing a limited number of species 1350 (Fed. Cir. 2004)



"[T]he PTO would find compliance with 112, paragraph 1, BioChem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 964 (Fed. Cir. 2002). antigen X, notwithstanding the functional definition of the functional characteristics of antibody binding, and the fact mature." Noelle, 355 F.3d at 1349 (Fed. Cir. 2004) (quoting Enzo for a claim to an isolated antibody capable of binding to that the antibody technology is well developed and characteristics for the five classes of antibody, the antibody, in light of the well defined structural



2003) (emphasis added)." <u>Noelle</u>, 355 F.3d at 1350 (Fed. Cir. 2004). binding to antigen X' would have sufficient support in a "A claim directed to 'any antibody which is capable of http://www.uspto.gov/web/menu/written.pdf (last visited Jan. 16, written description that disclosed 'fully characterized antigens.' Synopsis of Application of Written Description Guidelines, at 60, available at

"Therefore, based on our past precedent, as long as an applicant has disclosed a "fully characterized antigen," properties, or by depositing the protein in a public depository, the applicant can then claim an antibody by its binding affinity to that described antigen." Noelle, 355 either by its structure, formula, chemical name, or physical F.3d at 1349 (Fed. Cir. 2004) (emphasis in original).



The Decision

- Noelle did not describe human CD40CR antigen.
- Noelle cannot claim an unknown by its binding to an unknown.
- CD40CR antigen, he could have claimed its antibody by If Noelle had sufficiently described the human form of simply stating its binding affinity for the "fully characterized" antigen.
- Noelle cannot claim the genus form of CD40CR antibody by simply describing mouse CD40CR antigen given the state of the art at the time the applications at issue were

Noelle, 355 F.3d at 1349-50 (Fed. Cir. 2004).

Written Description

Antibodies





The Claim

An antibody that specifically binds an isolated polypeptide that comprises an immunogenic fragment of SEQ ID NO: 1.



The Specification

Discloses only one species of polypeptide, i.e. SEQ. ID. NO:1.



Written Description

- for the genus of antibodies specifically binding the genus of polypeptides that comprise immunogenic description for antibodies which specifically bind polypeptides comprising SEQ ID NO: 1 but not In this fact pattern, there is adequate written fragments.
- Note that the term comprises opens the claim to attached to other nondisclosed polypeptides. include the fragment being embedded in or

Prior Art

Antibodies





Claim

binds a fusion protein comprising SEQ ID An isolated antibody which specifically NO: 1.



The Specification

- Discloses an isolated full length polypeptide of SEQ ID NO: 1.
- Discloses an antibody raised to the full length polypeptide.
- Discloses fusion proteins comprising SEQ ID NO: 1 and heterologous polypeptides selected from HIS tags and BSA.



Prior Art

specifically bind HIS tags for use in protein Reference X teaches antibodies which purification.



Conclusion

U.S.C. 102 over the prior art reference X antibodies which would specifically bind The claim would be rejected under 35 the instantly claimed fusion protein.



The Claim

binds to a polypeptide comprising SEQ ID An isolated antibody which specifically NO: 1:



The Specification

- Discloses an isolated full length polypeptide of SEQ ID NO: 1.
- Discloses an antibody raised to the full length polypeptide.



Prior Art

- Reference Y teaches a protein that is 99% identical to SEQ ID NO: 1 over its full length.
- Reference Y also teaches an antibody that was raised to and specifically binds said protein of the art.

Rejection under 35 U.S.C. 102

- interpretation, defines the act of an antibody binding to its Specifically binds, given its broadest reasonable
- characteristic, and is specific for the antibody binding site. Antibody binding to related antigens is a known
- to raise the instantly claimed antibody, indeed, it is nearly The antigen of the art is highly related to the antigen used identical.
- rejection under 35 U.S.C. 102 over the claimed antibody. The antibody of prior art reference Y would support a

This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

Defects in the images measure out the net immediate the fields encoded.
D BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
·

IMAGES ARE BEST AVAILABLE COPY.

OTHER:

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.